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OCT 26 2007

Applicant:	KaVo Dental Corporation
Address:	340 East Main Street Lake Zurich, IL 60047 USA
Phone Number:	847-550-6800
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Contact Person:	Mari Lambert
Summary Prepared:	October 4, 2007
Name of Device:	KaVO GENTLEray 980
Trade Name:	GENTLEray 980
Common Name:	GENTLEray
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
CFR Number:	21 CFR §878.4810
Product Code:	GEX
Product Description:	The GENTLEray 980 Diode Dental Laser System is a portable instrument intended for ablating, incising, excising, and coagulating intraoral soft tissue (including the marginal and interdental gingiva) using a contact fiber optic delivery system.
Intended Use:	Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue. The GENTLEray 980 Diode Dental Laser System is intended for use in the following procedures: Frenectomy, Frenotomy, Biopsy, Operculectomy, Implant Recovery, Gingivectomy, Gingivoplasty, Gingival Troughing, Crown Lengthening, Hemostasis of Donor Site, Removal of Granulation Tissue, Laser-assisted Flap Surgery, Debridement of Deseased Epithelial Lining, Incisions and Draining of Abscesses, Tissue Retraction for Impressions, Papillectomy, Vestibuloplasty, Excision of Lesions, Leukoplakia, Exposure of Unerupted/Partially Erupted Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an Adjunct to Root Canal Therapy, and Light Activation of Bleaching Materials.

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Performance Standards: The GENTLEray 980 Diode Dental Laser System complies with the appropriate sections of 21 CFR §1010 and 21 CFR §1040.

Substantial Equivalence: The GENTLEray 980 Diode Dental Laser System has the same intended use and the same or substantially equivalent technical specifications and mechanism of action as compared with the named predicated devices. The KaVo GENTLEray 980 Diode Laser is substantially equivalent to the Ceramoptec Ceralas D15 (K983058, K991891) sold latterly under the BioLitec brand name SmilePro™ 980, the ADT Diolase 980 D Laser System (K023547) and the Elexxion Claros (K063152). Performance testing to validate the safety and effectiveness of the GENTLEray 980 Diode Dental Laser System includes electrical safety, electromagnetic compatibility, and validation testing of both hardware and software functions. The comparison of specifications are as follows:

	Proposed Device	Predicate Device	Predicate Device	Predicate Device
Specifications	KaVo GENTLEray 980	Biolitec Smilepro 980	ADT Diolase 980 D	Elexxion Claros
Wavelength	980 nm	980 nm	980 nm	810 nm
Output Power	12W	15W	15 W	30 W
Power Range	.4 - 12W	1-15W	.2 - 15 W	0.01W – 30 W
Increments	.2 - 1W	1W	.2 - 1W	0.01W – 1 W
Operating Modes	Pulsed or Continuous	Pulsed or Continuous	Pulsed or Continuous	Pulsed or Continuous
Pulse Duration ON	25µs to 99.9 Sec.	0.01 to 99.9 Sec.	0.01 to 99.9 Sec	25µs to 99.9 Sec.
Pulse Duration OFF	25µs to 99.9 Sec.	0.01 to 99.9 Sec.	0.01 to 99.9 Sec	25µs to 99.9 Sec.
Frequency	20.000 Hz	100 Hz	100 Hz	20.000 Hz
Aiming beam	635 nm, <1mW; Red	635 nm, 4mW; Red	635 nm, 4mW; Red	635 nm, 4mW; Red
Cooling	Air Cooled	Air Cooled	Air Cooled	Air Cooled
Weight	9 lbs. (4.5kg)	15 lbs. (9kg)	11 lbs. (5kg)	48 lbs. (22kg)
Dimensions	10.5" x 7" x 6"	14" x 9" x 7"	14" x 9" x 3"	33" x 18" x 20"
Power Requirements	100 - 240 V	110/220 V	110/220 V	110/220 V
Sterilization Methods	Steam Autoclave	Steam Autoclave	Steam Autoclave	Steam Autoclave
Irrigant Supply	Peristaltic Pump	Peristaltic Pump	Peristaltic Pump	None
Indications for Use	Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue. The device is intended for use in the following procedures: Frenectomy, Frenotomy, Biopsy, Operculectomy, Implant Recovery, Gingivectomy, Gingivoplasty, Gingival Troughing, Crown Lengthening, Hemostasis of Donor Site, Removal of Granulation Tissue,	Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue. The device is intended for use in the following procedures: Frenectomy, Frenotomy, Biopsy, Operculectomy, Implant Recovery, Gingivectomy, Gingivoplasty, Gingival Troughing, Crown Lengthening, Hemostasis of Donor Site, Removal of Granulation Tissue,	Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue. The device is intended for use in the following procedures: Frenectomy, Frenotomy, Biopsy, Operculectomy, Implant Recovery, Gingivectomy, Gingivoplasty, Gingival Troughing, Crown Lengthening, Hemostasis of Donor Site, Removal of Granulation Tissue,	Dental **Soft** Tissue Indications Including Pulpal Tissues* Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including: Excisional and incisional biopsies, Exposure of unerupted teeth, Fibroma removal, Frenectomy, Frenotomy, Gingival troughing for crown impressions, Gingivectomy, Gingivoplasty, Gingival

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	Laser-assisted Flap Surgery, Debridement of Deseased Epithelial Lining, Incisions and Draining of Abscesses, Tissue Retraction for Impressions, Papillectomy, Vestibuloplasty, Excision of Lesions, Leukoplakia, Exposure of Unerupted/Partially Erupted Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an Adjunct to Root Canal Therapy, and Light Activation of Bleaching Materials.	Laser-assisted Flap Surgery, Debridement of Deseased Epithelial Lining, Incisions and Draining of Abscesses, Tissue Retraction for Impressions, Papillectomy, Vestibuloplasty, Excision of Lesions, Leukoplakia, Exposure of Unerupted/Partially Erupted Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an Adjunct to Root Canal Therapy, and Light Activation of Bleaching Materials.	Laser-assisted Flap Surgery, Debridement of Deseased Epithelial Lining, Incisions and Draining of Abscesses, Tissue Retraction for Impressions, Papillectomy, Vestibuloplasty, Excision of Lesions, Leukoplakia, Exposure of Unerupted/Partially Erupted Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an Adjunct to Root Canal Therapy, and Light Activation of Bleaching Materials.	incision and excision, Hemostasis and coagulation, Implant recovery, Incision and drainage of abscesses, Leukoplakia, Operculectomy, Oral papillectomies, Pulpotomy, Pulpotomy as an adjunct to root canal therapy, Reduction of gingival hypertrophy, Soft tissue crown lengthening, Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa, and Vestibuloplasty. *For use on adult and pediatric patients **Laser Periodontal** Procedures Laser soft tissue curettage, Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket, Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium, Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility) **Tooth Whitening** Laser assisted whitening/bleaching of teeth, Light activation for bleaching materials for teeth whitening.

Conclusion: After analyzing both bench and user testing data, it is the conclusion of Kavo that the GENTLEray 980 Diode Laser System is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kavo America
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

OCT 26 2007

Re: K072262
Trade/Device Name: GENTLEray 980 Diode Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 10, 2007
Received: October 11, 2007

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072262

Device Name: GENTLEray 980 Diode Laser System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072262